

June 15, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 99D-0557

This letter is written in protest and disgust in response to a Food and Drug Administration (FDA) "industry guidance" notice published in the Federal Register on "Public Health Issues Posed by the Use of Non-human Primate Xenografts."

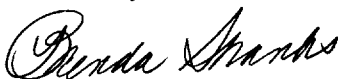
If the FDA has implemented a ban on the transplantation of vital organs, cells, and tissues from non-human primates to humans due to "significant infectious disease risk", how can they justify the dangers posed by transplants from other species.

Pigs, having become the species of choice among the various companies vying for a piece of the animal organ market, pose an equally significant risk to human health. Pigs carry a number of known as well as unknown viruses that could "jump" from one species to another as a result of xenografts. When it was discovered that pigs carry a pair of viruses called porcine endogenous retrovirus-A and-B and that both viruses belong to a family that includes the human immunodeficiency virus (HIV), which causes AIDS and both can infect human cells, this species of organ donor and any idea in any way related should have been thrown out the window.

In 1998, General Accounting Office report on organ donation revealed an untapped donor pool of 150,000 people annually. What is the problem here? We have a pool of organ donors available at our fingertips and we are wanting to branch out to pigs?? Countries like Spain, Austria, and Belgium have much higher donation rates than the U.S. due in part to the fact that European organ donor policies assume that every person is an organ donor unless otherwise specified. They are way ahead of us in this game. Maybe we should think twice about this whole business of organ transplants and put the funding dollars to work on the many promising new treatments for AIDS and other life-threatening diseases and work on utilizing and expanding our "donor pool".

Please consider banning xenotransplantation immediately and forever.

Sincerely,

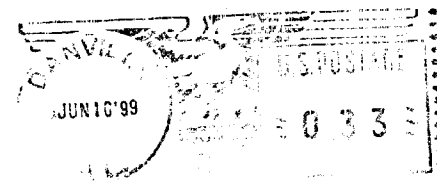


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